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Ref: REQUEST FOR THE REHEARING Appeal no. 2005-2478

Appeal No. 2005-2478

Application No. 09/591,009

Appellant: Ashok K. Shukla et.al.

Decision of Appeal mailed on Nov. 30, 2005, after hearing
on Nov. 15, 2005., before the Judges; OWENS, KRATZ and
FRANKLIN

Herewith, I request for the rehearing of above case due to
following argument.

Background

Claim 1. In the original application filed on 06/09/00

1. A pipette tip which has an upper end and a lower end and
which has one or more perforations or incisions at the
lower end to permit the selective passage of smaller
particles or fluids through said perforations or
incisions while retaining larger particles in the tip.

Amended Claim submitted after interview with the Examiner
on 04/04/02

(Marked version) A pipette tip for sample preparation,
which contains [a] chromatography [or separation material]
particles and has an open upper end and a closed lower end
and has one or more perforations [or incisions] at the said
lower end to permit the [selective] passage of [smaller
particles or] fluids through said perforations [or
incisions] while retaining [larger] chromatographic
particles in the said pipette tip.

(Clean version) A pipette tip for sample preparation, which contains chromatography particles and has an open upper end and a closed lower end and has one or more perforations at the said lower end to permit the passage of fluids through said perforations while retaining chromatographic particles in the said pipette tip

Amended claim submitted to Wand Walker, SPE on Sept 18, 2002.

A pipette tip for sample preparation, which contains chromatography particles and has an open upper end and a closed lower end and has one or more perforations at the said lower end to permit the passage of fluids through said perforations while retaining said chromatographic particles in the said pipette tip, said chromatographic particles are larger than the said perforations.

Decision of appeal has emphasis on the claim 1 and affirmed the examiner's rejection based on the Valaskovic (6,190,559) patent description not the claim.

In our invention original application we described on page 4 line 14-17,

The perforations, holes or incisions are of such dimensions that fluids and smaller particles can pass through while larger particles are retained in the container.

In page 6 line 17-20.

The lower end contains one or more perforations or incisions (4) designed to permit the selective passage of smaller particles or fluids through said perforations or incisions (4) while retaining larger particles in said tip (1).

In application page 10 line 23-29

In this instance, a 10-200 micro-liter micro pipette tip was sealed closed at its bottom end. A 2 milli-meter long and 10 micron wide incision was made at the bottom end of the tip, using a sharp blade to create the slit. A 50 micro-liter slurry of C-18 column material (with particle sizes of 40-60 microns) was introduced into the tip through the top open end.

Fig. 2, 3 and 4. show that particles are larger than the slit or perforation.

Further when we filed our patent we were not aware of Valaskovic (6,190,559) patent.

Intention of our invention was always clear that the particles are larger than the perforation, and we describe multiple times in our descriptions, as well as in drawings clearly that the particles are larger than the perforation. Therefore, defining the same embodiment in the description is a part of the patent and not a new issue. We wrote this argument in our correspondence with the examiner.

For example we wrote to examiner on 04/04/02

"We have made changes in our application and narrowed down claim 1 as suggested by examiner during the interview, to overcome the US patent No. 6,190559. As Valaskovic (Column 2, line 4-7) teaches, a filling of packing material in slurry form in a column by capillary action, then removing the solvent by evaporation and then optionally sintering the end to hold the packing material inside the capillary column. The end from which the column material (slurry) was loaded has to be sintered because the column material will otherwise flow out with the sample or the solvent and will not stay in the column. In our pipette tip, we load the solution into the tip using a pipette or a syringe and the packing material does not flow out of the column because the end of column from which the solution or sample is loaded (or aspirated) has a very small slit such that the chromatographic particles cannot pass through it but the solvents can. Thus no sintering is needed and the chromatographic particles stay inside the column. Whereas, in the Valaskovic column, the packing material has to be sintered to prevent it from flowing out. Our device is clearly different from his where we first take a column or tube with one closed end and fill it with chromatographic particle and then make a very small slit whose width is smaller than the size of chromatographic particles so that the material is not lost during sample preparation. and the solution can flow freely through the pipette tip."

Examiner has done the search based on the original claim that particles are larger than the perforation. However, after we talked to Mrs. Walker and sent her the amended

claim, the examiner pointed out that this was a new issue, however it was the original patent.

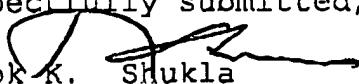
In our reply of 4/4/02 after an interview and demonstration of the device and the first office action, we tried to amend the claim (1) in such a way that the perforation is smaller than the particles and not to use the smaller particles in the claim, so that the particles are placed in the tip from the other end not from the side of the perforation. This is the main difference between our invention and Valaskovic (6,190,559) patent. In Valaskovic patent the slurry contains all the particles smaller than the perforation, otherwise they cannot pass through the perforation to form a bed in the tip which is afterward sintered.

Therefore, we request you to consider our appeal for rehearing and to understand the basic difference between our invention and Valaskovic patent, because these two inventions are completely different from each other and each has described the limitation of the particle size to perform the work as described in the claims and invention description, respectively.

Herewith, a copy of letter from Dr. Robert Stevenson, is attached to demonstrate the novelty of the invention.

Thank you in advance for all your cooperation.

Respectfully submitted,


Ashok K. Shukla

10316 Kingsway Court
Ellicott City, MD 21042

Tel: 410-465-2212 (day time) 410 997-0301)
Fax: 410-997-0772.

ISC

**International
Scientific
Communications, Inc.**

Ashok Shukla, Ph. D.
President and Founder
Glygen Corp.
8990 Route 108, Suite C-1
Columbia, MD 21045, USA

ROBERT STEVENSON, Ph. D.
EDITOR OF SEPARATION SCIENCE

3338 CARLYLE TERRACE
LAFAYETTE, CA 94549
PHONE (925) 283-7619
FAX (925) 283-5621
EMAIL rsteven@comcast.net

November 14, 2005

Dear Dr. Shukla

I'm responding to your request for an analysis of the novelty and utility of the TopTip from Glygen.

Utility: The TopTip is a filterless chromatographic Tip for sample preparation. The design of TopTip includes a very narrow slit across the bottom of the tube or pipette tip. The slit retains the chromatographic particles larger than the slit size. However, the slit permits the passage of liquids and solvents. This feature facilitates solid phase extraction (SPE) with almost any adsorbent.

As practiced with prior technology, SPE is performed with sample size in the range of 50 μ l or larger due to the volume of the filter. With TopTip, the sample volume can be reduced to 100 nL or perhaps less because no filter is required. This reduced size is much more compatible with the low micro liter to nanoliter volumes that analysts intend to use today and going forward. Thus TopTip should be seen as a new key enabling technology.

Another advantage is that the TopTip is very easy to use. There is no need to monitor the wetting of the bed as with other SPE devices. Simply put the sample in the TopTip tube, agitate to mix, spin a few seconds (or push with a micropipettor), add the elution liquid, agitate, add a collection tube, spin again for a few seconds, and one has the clean extraction the bottom tube. The entire process can be done with unskilled labor in less than two minutes total elapsed time.

Novelty: I've been involved in chromatography since 1958. I've never seen anything similar to the design of the TopTip. The fact that it can separate the liquid from the solid in SPE without a filter reduces the size, cost and avoids any concern of nonspecific binding on the filter.

Publishers of: American Laboratory, Journal of Capillary Electrophoresis, Managing the Modern Laboratory, American Biotechnology Laboratory

In summary, based upon my 47 years of experience in designing and reporting on products for chromatography, the TopTip is indeed both novel and useful. I'm confident that its use will grow as more people become aware of it.

If there are any questions, please call me.

Sincerely

**Robert Stevenson, Ph. D.
Editor of Separation Science**

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